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Lori White
NTP Office of Liaison
Policy and Review, NIEHS
P.O. Box 12233, K2-03
Research Triangle, NC 27709.

Re: Comment on the NTP Draft Brief
on Soy Formula (March 2010)

Dear Dr. White:

I am the Principal Investigator on a prospective and longitudinal clinical study of children (birth to age 6 years) who are fed soy formula. This study addresses important issues, such as the effects of infant feeding on; growth, development, body composition, metabolism, endocrine status, reproductive organ sizes, brain development, cognitive function, learning abilities, attention, language acquisition, and behavioral development. I attended the December 2009 meeting in which the draft brief was formulated and I presented data on ultrasonography of reproductive organs in children fed soy formula in comparison to infants fed breast milk or milk-based formula. The study showed **reproductive organ sizes of soy-fed infants do not differ from breast-fed or milk-fed infants**. The Panel judged the results to be "no utility", claiming that not enough children were fed soy formula from birth and also saying that the statistics were incorrect. However, the mean results of children fed soy formula from birth were almost identical to those of children starting soy formula later; the data were tight and it did not matter whether ANOVA or t-testing was used, the outcomes were the same. **The NTP Draft Brief should have given these results from this high-quality, well-controlled prospective study on infants fed soy formula more consideration.**

The heavy reliance of the NTP Draft Brief on studies of purified isoflavones is a true travesty. As all toxicologists recognize, the effects of one compound can be greatly affected by the presence or absence of other compounds. **This is a basic premise in toxicology.** The study of a single compound, genistein, out of the context of how it is normally consumed in soy formula, can lead to results and conclusions that do not apply to the soy formula. It has been shown over and over again that the effects of a single dietary compound isolated from the parent food can result in reaching false conclusions. **Thus, one important limitation of the NTP Draft Brief is the use of aglycones to mimic soy formula.**

Rodents have limited use (utility) in identifying the effects of soy formula because it is very difficult to "bottle feed" a newborn rat or mouse. In fact, **there have been no published studies of newborn rodents fed soy formula**. Furthermore, injecting isoflavones into pregnant or baby rodents simply does not model feeding soy formula to human infants, either on the basis of diet composition or the stage of life in which such challenges are given. Such experiments would only model human infants of mothers who were injected with isoflavones during pregnancy or breast-fed babies injected with pure isoflavones during the immediate post-natal period.

Sincerely,
(Redacted)

Thomas M. Badger, PhD
Professor
Department of Pediatrics and Physiology/Biophysics
Director
Arkansas Children's Nutrition Center